# Complete Summary

## GUIDELINE TITLE

Colon cancer.

## BIBLIOGRAPHIC SOURCE(S)

Colon cancer. Philadelphia (PA): Intracorp; 2005. Various p. [31 references]

## GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2005 to July 1, 2007.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Colon cancer also known as colorectal cancer (or carcinoma)

### GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Screening
Treatment

### CLINICAL SPECIALTY

Colon and Rectal Surgery
Family Practice
Gastroenterology
Internal Medicine
Oncology

## INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

## GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, management, and treatment of colon cancer that will assist medical management leaders to make appropriate benefit coverage determinations

## TARGET POPULATION

Individuals with or at risk of colon cancer

## INTERVENTIONS AND PRACTICES CONSIDERED

### Diagnosis/Evaluation/Risk Assessment/Screening

1. Physical examination and assessment of signs and symptoms
2. Risk assessment
3. Diagnostic/screening tests:
    - Digital rectal exam (DRE)
    - Fecal occult blood test (FOBT)
    - Barium enema (BE) with or without contrast
    - Sigmoidoscopy (rigid or flexible fiber optic)
    - Colonoscopy (or colon endoscopy) with biopsy
    - Computed tomography (CT)
    - Transrectal ultrasound (TRUS)
    - Magnetic resonance imaging (MRI)
    - Laparotomy
    - Blood work (complete blood count [CBC], liver chemistries, carcinoembryonic antigen level [CEA])
    - C-reactive protein (CRP)
    - Genetic testing

### Management/Treatment

1. Screening, diagnostic surveillance
2. Surgical excision including
    - Hemicolectomy

    - Low anterior resection (LAR)
    - Abdominoperineal resection (APR)
    - Local excision for palliative treatment or polyp removal
3. Radiation therapy
4. Chemotherapy
5. Electrocoagulation
6. Pain control
7. Nutrition therapy
8. Physical therapy
9. Referral to specialists
10. Case management strategies, including case initiation, case management focus, and discharge

### MAJOR OUTCOMES CONSIDERED

- Risk factors for colon cancer
- Incidence of colon cancer
- Survival rates

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

#### Diagnostic Confirmation

##### Subjective Findings

- May be asymptomatic
- Complaint of frequent gas pains, bloating, fullness, and/or cramps
- Spasms at anus or bladder (tenesmus)
- Abdominal mass and/or pain
- Changes in bowel habits:
    - Pencil-thin bowel movements
    - Constipation
    - Diarrhea
    - Bleeding per rectum
- Anorexia or early satiety
- Vomiting
- Unintentional weight loss
- Lethargy
- Weakness
- Palpitations

##### Objective Findings

- Mass on digital rectal exam (DRE)
- Bright red blood per rectum
- Other symptoms of lower gastrointestinal (GI) bleeding:
    - Tarry black stools
    - Hypochromic, microcytic anemia on complete blood count (CBC) (chronic bleed)
- Streptococcus bovis bacteremia, highly suggestive of occult colonic tumor

##### Diagnostic Tests

American Cancer Society and Centers for Disease Control and Prevention guidelines for colon cancer screening in all adults aged 50 years or older:

- Fecal occult blood test (FOBT) every year
    - Occult stool testing must be repeated at least 3 times on different stool samples.
    - Diet must be free of peroxidase activity (turnips & horseradish).
    - Tests may need to be repeated if there is a history of:
        - Usage of possible gastric irritants such as salicylates, other antiinflammatory agents
        - Hemorrhoids
        - Diverticulitis
        - Peptic ulcer disease (PUD) or other cause of GI bleeding
- Flexible sigmoidoscopy every five years
- Double-contrast barium enema every five years

- Colonoscopy every ten years

Colorectal cancer screening is considered medically necessary for increased or high-risk women and men, with one of the following risk factors:

- A first-degree relative (sibling, parent, child) who has had colorectal cancer or an adenomatous polyp, screening should begin at age 40 years or
- Family history of familial adenomatous polyposis (FAP) screening should begin at puberty:
    - Sigmoidoscopy - annually, beginning at age 10 to 12 years
    - Colonoscopy - every five years
- Family history of hereditary nonpolyposis colorectal cancer (HNPCC) screening should begin at age 21 years:
    - Sigmoidoscopy - annually, beginning at age 10 to 12 years
    - Colonoscopy - every one to two years, beginning at age 20 to 25 years or 10 years younger than the earliest case in the family, whichever comes first
- Personal history of adenomatous polyps:
    - One or more adenomatous polyps removed at the time of the colonoscopy, screening should be managed according to the pathological findings
    - Numerous adenomas, a malignant adenoma (with invasive cancer), a large sessile adenoma, or an incomplete colonoscopy should have a short interval follow-up, based on pathological findings
    - Advanced or multiple adenomas (equal to or greater than 3), first follow-up colonoscopy should occur in three years
    - One or two small (less than 1 centimeter) tubular adenomas, first follow-up colonoscopy should occur at five years
    - On-going surveillance after first follow-up colonoscopy, if the colonoscopy is normal or only one or two small (less than once centimeter) tubular adenomas are found, the next colonoscopy can be in five years.
- Personal history of colorectal cancer:
    - After colon resection, with curative intent, then approximately six months after the surgery or
    - Surveillance after colorectal cancer, if the colonoscopy performed at six months or a complete preoperative examination is normal, subsequent colonoscopy should be repeated at three years and then if normal, every five years.
- Personal history of inflammatory bowel disease:
    - For surveillance
        - Every one to two years after an eight year history of the disease with pancolitis or
        - Every one to two years after 15 years history of left-sided colitis or
    - For all patients beginning with eight to ten years of disease to document the extent of the disease
- Digital rectal exam (DRE)
- Barium enema (BE) with or without air contrast
    - BE is used primarily for screening purposes to locate deformities of intestinal topography.
- Sigmoidoscopy, rigid type or flexible fiber optic type

    - Sigmoidoscopy is used to visualize local rectal tumors or for routine screening.
- Colonoscopy (or colon endoscopy) [see the Intracorp guideline Colonoscopy]
    - Direct visual examination of the lower colon and rectum detects early polypoid tumors preoperatively and recurrences post-resection.
    - Multiple biopsies may be performed at time of study to increase sensitivity.
- Computed tomography (CT) [see the Intracorp guideline Imaging: abdominal & viscerae]
    - CT scan is used to stage disease and identify metastases.
- Transrectal ultrasound (TRUS) [see the Intracorp guideline Imaging: abdominal & viscerae]
    - Sonograms are an excellent choice for preoperative staging of rectal carcinomas.
- Magnetic resonance imaging (MRI) [see the Intracorp guideline Imaging: abdominal & viscerae]
    - MRI is very useful for diagnosing metastatic disease.
- Laparotomy
    - Laparotomy can be useful in detecting metastases to abdominal regions (especially omentum or liver) that often remain undetected by current imaging techniques.
- Blood work that may be indicated:
    - Complete blood count (CBC)
        - Critical values: hemoglobin (Hgb) <9 gm/dl; hematocrit (Hct) <25 volume %; platelets (Plts) <30,000/$mm^3$.
        - Hct <30 volume % indicates moderate to severe anemia.
        - Anemia can contribute to multisystem symptoms, such as confusion, congestive heart failure, fatigue, and shortness of breath
    - Liver chemistries:
        - Alkaline phosphatase (ALP); Normal value: Adult: 17-142 U/L
        - Glutamyl transferase (GGT); Normal value: Adult Men: 5-85 U/L, Women: 5-55 U/L
        - Abnormal liver enzyme results may suggest metastatic disease.
    - Carcinoembryonic antigen level (CEA); Normal value: 0-2.5 mg/ml; up to 10 mg/ml in tobacco smokers
        - Serum CEA is useful in establishing diagnosis and recurrence for tumors that secrete CEA and in following disease progression.
        - Because colon lesions are not likely to secrete CEA, it is not a highly reliable indicator of colon cancer.
        - If CEA is elevated, return to normal levels is expected to occur within 48 hours after complete tumor excision.
- C-Reactive protein (CRP)-recent studies have shown that increased plasma concentrations of CRP are associated with subsequent development of colon cancer.
    - Preliminary findings are consistent with the established association between colon cancer and inflammatory bowel disease (IBD).
    - CRP research is ongoing and full corroboration of suggestive findings has not been established as of this writing.
- Genetic testing
    - Genotyping (APC gene test) should only be used when other diagnostic avenues are exhausted; however, it is medically necessary in presence

of strong family history for familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), or hereditary nonpolyposis colorectal cancer (HNPCC).

### Differential Diagnosis

- Arteriovenous malformations
- Diverticulosis (see the Intracorp guideline Diverticular Disease)
- Diverticulitis with abscess formation (see the Intracorp guideline Diverticular Disease)
- Adenomatous polyps-
    - Premalignant neoplasm
    - Morphological types- tubular, tubulovillous, villous
- Ischemic colitis
- Infarcted colon
- Megacolon
- Hemorrhoids (see the Intracorp guideline Hemorrhoids)

## Treatment

### Treatment Options

- Screening, diagnostic surveillance
    - Care Setting: clinic, free-standing outpatient, or physician's office
- Surgical excision:
    - Hemicolectomy
    - Low anterior resection (LAR)
    - Abdominoperineal resection (APR), requires permanent colostomy
        - Care Setting: acute inpatient; anticipated length of hospital stay would be 7 or 8 days
    - Local excision, for palliative treatment or simple polyp removal
        - Care Setting: clinic, free-standing outpatient, or physician's office unless acute illness or self-care deficit warrants subacute/skilled nursing facility inpatient or hospice inpatient admission - anticipated length of stay would be 2 or more days
- Radiation therapy, done in series of treatments and repeated as needed
    - Care Setting: clinic or free-standing outpatient unless acute illness or self-care deficit warrants acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient admission
- Chemotherapy (see the Intracorp guideline Chemotherapy)
    - Care Setting: clinic or free-standing outpatient, physician's office, or home care unless acute illness or self-care deficit warrants acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient admission
- Electrocoagulation
    - Mostly palliative treatment for rectal carcinomas; curative for small subset of patients
    - Care Setting: clinic, physician's office, or free-standing outpatient unless acute illness or self-care deficit warrants acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient admission
- Pain control, maintenance at least invasive level possible

    - Care Setting: home care or physician's office unless acute illness or self-care deficit warrants acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient admission
- Nutrition therapy, maintenance at least invasive level possible
    - Care Setting: self-administered, physician's office or home care unless acute illness or self-care deficit warrants acute inpatient, subacute/skilled nursing facility inpatient, or hospice inpatient admission

Duration of Medical Treatment

- Medical - Optimal: 45 day(s), Maximal: 90 day(s)
    - Factors influencing the duration are the stage of the carcinoma, presence of metastatic disease, and level of comorbid disease.
- Surgical - Optimal: 30 day(s), Maximal: 120 day(s)

Additional information regarding primary care visit schedules, referral options, specialty care, physical therapy, and durable medical equipment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- After diagnostic sigmoidoscopy or colonoscopy
- After hospitalization and resection with colostomy
- After hospitalization and colectomy
- After chemotherapy and/or radiation therapy

Note: Some patients with this condition may never return to work.

Case Management Directives (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- See Chemotherapy Chart in the original guideline document.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

- Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound (based on most recent performance status) and interventions required.

Chemotherapy Intolerance

- Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

- Document bleeding complications, severity, and intervention recommended.

Immune Compromised

- Document establishment of protective isolation measures for a white blood cell count (WBC) less than 1,000/$mm^3$, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe, and response needed.

Mental and Emotional Alteration

- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.
- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline document through benefit coordination or community resource activation.

Pain Control

- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate emergency medical technician (EMT) system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

- Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Document severity of skin integrity disruption.

Terminal Care

- Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

- Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate diagnosis, management, and treatment of colon cancer that assist medical management leaders to make appropriate benefit coverage determinations

### POTENTIAL HARMS

Not stated

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness
Staying Healthy

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Colon cancer. Philadelphia (PA): Intracorp; 2005. Various p. [31 references]

### ADAPTATION

The guideline recommendations on colon cancer screening in all adults aged 50 years or older are partially adapted from the following:

- Morantz C, American Cancer Society. ACS Guidelines for Early Detection of Cancer. Am Fam Physician. 2004 Apr 15;69(8):2013.
- Center for Disease Control and Prevention, U.S. Department of Health and Human Services. Colorectal Cancer Prevention and Control Initiatives. Screen for Life. Atlanta (GA): Center for Disease Control and Prevention. 2005 May.

### DATE RELEASED

2005

### GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

### SOURCE(S) OF FUNDING

Intracorp

### GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

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## GUIDELINE AVAILABILITY

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## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI on August 10, 2005. The information was verified by the guideline developer on August 31, 2005.

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